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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/813,081	03/29/2004	Ella Magal	A-504C	4278
7590 03/02/2005			EXAMINER	
AMGEN, INC. U.S. Patent Operations/JWB Dept. 4300, M/S 27-4-A One Amgen Center Drive Thousand Oaks, CA 91320-1799			CHANG, CELIA C	
			ART UNIT	PAPER NUMBER
			1625	
DATE MAILED: 03/02/2005				

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/813,081

Applicant(s)

MAGAL, ELLA

Examiner

Celia Chang

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on 26 March 2004.  
2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.  
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☐ Claim(s) 1-171 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.  
7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.  
8) ☐ Claim(s) 1-171 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.  
10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)  
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.  
4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_.  
5) ☐ Notice of Informal Patent Application (PTO-152)  
6) ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

1. Claims 1-171 are in the case.

2. ***Election/Restrictions***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-57, drawn to method of treating sensorineural hearing loss, classified in class 514, subclass various, depending on species election. If this group is elected, a further election of a single disclosed species of active compound for treating sensorineural hearing loss is also required. Further restriction based on the species election will be required.
- II. Claims 58-114, drawn to method of treating injury or degeneration of inner ear, classified in class 514, subclass various, depending on species election. If this group is elected, a further election of a single disclosed species of active compound for treating sensorineural hearing loss is also required. Further restriction based on the species election will be required.
- III. Claims 115-171, drawn to method of treating vestibular disorder, classified in class 514, subclass various, depending on species election. If this group is elected, a further election of a single disclosed species of active compound for treating sensorineural hearing loss is also required. Further restriction based on the species election will be required.

The inventions are distinct, each from the other because:

Method of treating the different disorders of groups I-III are independent and distinct because it is evidence in the art that sensorineural hearing loss can be with or without vestibular symptoms, thus, such method do not share the same etiology or symptoms (see CA 129:53284). Treating independent disorder or symptom must be searched and examined separately since factual evidence in the art indicated that groups I-III are not so linked as to related with each other in an inexorably manner that modification of any one pathway would inexorably resulting

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in modification of the others. Furthermore, an enormous amount of material being used for each independent method must be searched and examiner in relation to the particular steps and dosage for treating groups I-III disorders. Without a species election, the proper classification cannot be assigned.

A telephone call was made to J. Brook on Feb. 9, 2005 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Should applicant traverse on the ground that the group and/or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the groups and/or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention. In the instant case, then, there could have been no patentability of all the claims over US 6,331,537 since generically the compounds anticipating the instant claims have been used for treating hearing loss (see col. 1 line 22, col. 7 lines 5-col. 8 line 63).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

3. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celia Chang whose telephone number is 571-272-0679. The examiner can normally be reached on Monday through Thursday from 8:30 am to 5:00 pm.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang, can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications

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system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

*OACS/Chang*  
*Mar. 1, 2005*



*Celia Chang*  
*Primary Examiner*  
*Art Unit 1625*